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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/276,268	03/25/99	STRACHAN	L 11000/1037

HM12/0223

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EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 02/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/276,268	Strachan et al.
Examiner	**Group Art Unit**
DeCloux, Amy	1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-19* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-19* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2, 9 and 10 drawn to an isolated peptide and a composition thereof, classified in Class 530, subclass 350 and Class 514, subclass 12,

II. Claims 3-8 and 11, drawn to an isolated polynucleotide, an expression vector, a host cell and a composition thereof, classified in Class 536, subclass 23.1, and Class 435, subclasses 252.3 and 320.1,

III. Claim 12, drawn to a method for the treatment of an inflammatory disorder in a patient, classified in Class 514, subclass 12,

IV. Claim 13, drawn to a method for modulating growth of blood vessels in a patient, classified in Class 514, subclass 12,

V. Claim 14, drawn to a method for the treatment of a disorder of the immune system, classified in Class 424, subclass 185.1,

VI. Claim 15, drawn to a method for the treatment of cancer in patients, classified in Class 514, subclass 12,

VII. Claims 16 and 17, drawn to a method for the treatment of a tumor necrosis factor-mediated disorder in a patient, classified in Class 514, subclass 12,

VIII. Claims 18 and 19, drawn to a method for the treatment of a viral disorder in a patient, classified in Class 514 , subclass 12.

3. These inventions are distinct, each from the other because of the following reasons:

A) Groups I and II are unique products. An isolated polypeptide and an isolated polynucleotide differ with respect to their physicochemical properties and are therefore patentably distinct.

B) Groups III-VIII and are unique methods. They differ with respect to their respective treatment endpoints. Therefore, they are patentably distinct each from the other.

C) Inventions I and III-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptide product as claimed can be used in a materially different process such as an immunopurification procedure.

D) Groups II and III-VIII are unrelated products and methods and are therefore patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any or these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

5. The applicant is further required under 35 U.S.C. 121;

A) If Group I is elected, to elect a **specific SEQ ID NO** from the group consisting of SEQ ID NO:11-20.

B) If Group II is elected, to elect a **specific SEQ ID NO** from the group consisting of SEQ ID NO:1-10.

C) If Group III, IV, V, VI or VIII is elected, to elect a **specific method** disclosed in the specification or recited in the claims (e.g. if Group VI is elected, to elect a **specific cancer** from the group consisting of epithelial, lymphoid, myeloid, stromal and neuronal cancers), **treated by a specific polypeptide,** (a specific SEQ ID NO: from the group consisting of SEQ ID NO:s 11-20).

D) If Group VII is elected, to elect a **specific method** (e.g. to elect a specific tumour necrosis factor-mediated disorder such as. arthritis, inflammatory bowel disease, or cardiac failure, as recited in Claim 17)

6. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. The following claim(s) are generic: claims 1, 3, 12, 13, 14, 15, 16 and 18.

The species are distinct each from the other for the following reasons:

A) epithelial, lymphoid, myeloid, stromal and neuronal cancers are different diseases, with different etiologies, clinical presentations and treatment modalities,

B) arthritis, inflammatory bowel disease and cardiac failure are different disorders, with different etiologies, clinical presentations and treatment modalities,

C) the recited polynucleotide sequences encode different proteins which have different biochemical characteristics, structure and functions,

D) the recited polypeptide sequences have different biochemical characteristics, structure and functions.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
February 22, 2000

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800 1640